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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC., Plaintiffs, v. AMBU A/S, AMBU INC., and AMBU LTD., Defendants.	Civil Action No. 07 CV 1988 DMS (NLS) **PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT ON AMBU'S LANHAM ACT AND RELATED STATE LAW COUNTERCLAIMS FOR FAILURE TO ESTABLISH FALSE OR MISLEADING ADVERTISING**
AMBU A/S, AMBU INC., and AMBU LTD., Counterclaimants, v. THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC., Counter-Defendants.	**Date: September 25, 2009** **Time:1:30 p.m.** **Courtroom: 10, 2nd Floor** **Honorable Dana M. Sabraw** **REDACTED VERSION**

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I. PRELIMINARY STATEMENT

In May 2005, The Laryngeal Mask Company Ltd. and LMA North America, Inc. (collectively "LMA"), circulated a brochure that made certain comparisons between their laryngeal masks ("LMs") and the LMs sold by defendants/counterclaimants, Ambu A/S, Ambu Inc., and Ambu Ltd. (collectively "Ambu"). In particular, LMA stated that: (i) the design of Ambu's LMs causes the mask to sit higher in a patient's anatomy; (ii) the higher position may cause the cuff of Ambu's LM to press against the hyoid bone which may lead to nerve palsy; and (iii) the higher position may increase the risk that the Ambu mask will not properly seal, which could lead to gastric insufflation, regurgitation, and aspiration. Three years after learning of LMA's brochure, Ambu filed a counterclaim in this case asserting that LMA had violated the Lanham Act's prohibition on false advertising.

To succeed on its Lanham Act claim, Ambu must show that statements in LMA's brochure are false or misleading. Ambu cannot meet this burden. Indeed, there can be no genuine dispute that: (i) LMA's brochure is merely a summary of research conducted by a respected anesthesiologist; (ii) the underlying research has been independently published in an abstract, presented as a poster at a scientific conference, and reprinted as a chapter in a textbook; and, perhaps most importantly, (iii) Ambu's own internal "smoking gun" documents confirm that the claims made in the brochure are absolutely true. Because Ambu cannot raise a genuine issue of material fact as to the veracity of LMA's advertisements, LMA is not only entitled to summary judgment on Ambu's Lanham Act claims but is also entitled to dismissal of Ambu's state law claims as well.

II. STATEMENT OF RELEVANT FACTS

A. Laryngeal Mask Airway Devices

A LM is a medical device used to manage a patient's breathing during anesthesia. Declaration of Fred Berretta in Support of Plaintiffs' Memorandum of Points and Authorities in Support of Their Motion for Summary Judgment on Ambu's Lanham Act and Related State Law Counterclaims for Failure to Establish False or Misleading Advertising ("Berretta Decl."), Ex. 1

at ¶¶ 21-24. The device is comprised of a breathing tube at the end of which is a mask having an inflatable cuff. *Id.* at ¶¶ 23-24; *see also* Ex. 2 at LMA00006103-06. A LM is inserted through a patient's mouth and the tip of the cuff should rest on the upper esophageal sphincter, creating a "seal" around the laryngeal inlet that isolates a patient's respiratory tract (*e.g.*, the lungs) from the alimentary tract (*e.g.*, the stomach). Berretta Decl., Ex. 1 at ¶ 24. If the device is correctly positioned and achieves a proper seal, air will pass through the tube and into the lungs. *Id.*

The LM was invented by Dr. Archie Brain at the London Hospital, Whitechapel in 1981. Berretta Decl., Ex. 3 at LMA00004012; Ex. 4 at 12:13-18, 22:5-15; Ex. 5 at AMBU0113000; Ex. 6 at [redacted] 1981 and 1988, Dr. Brain conducted extensive testing and modification of the LM, including by practicing self-insertion of the prototypes he created. [redacted] 133:6-10. In 1988, the first commercial version of the mask – the Laryngeal Mask Airway or "LMA" – became available in the United Kingdom. [redacted] The "LMA Classic" was the first LM commercially available in the United States in 1991. [redacted] Currently, LMA distributes several LM models, including the Classic™ LM, the Unique™ LM (a disposable version of the Classic™ LM), and the ProSeal™ LM (which includes important improvements to the original device, such as a drain tube for extraction of stomach fluids).

[redacted]

B. Risks Associated with the Malpositioning of Laryngeal Masks

LMs are generally considered to be safe medical devices. [redacted] There are, however, certain well-known risks that can arise as the result of the malpositioning of a LM. In particular, if a device sits too high in a patient's anatomy, the tip of the cuff may not rest on the upper esophageal sphincter and therefore may not adequately seal the patient's laryngeal inlet from his esophagus (and therefore stomach). *Id.* at ¶ 37. In the absence of a proper seal, air passed though the LM can travel down the esophagus and into the stomach. *Id.* at ¶ 51. This is called "gastric insufflation." *Id.* An improper seal can also increase the risk of regurgitation and aspiration. Regurgitation occurs when fluids from a patient's stomach pass up through and escape out of the esophagus. *Id.* at ¶ 52. Aspiration occurs when the stomach fluids enter the lungs. *Id.* at ¶ 53.

If a LM is positioned too high in a patient, the cuff may also press on the hyoid bone. [redacted] Putting pressure on the hyoid bone can, in turn, cause the hypoglossal nerve to become compressed. [redacted] The hypoglossal nerve is the motor nerve that controls the muscle function of the tongue. *Id.* at ¶ 42. If the hypoglossal nerve is damaged due to pressure from the hyoid bone, then tongue movement, speaking, and swallowing are affected. *Id.*

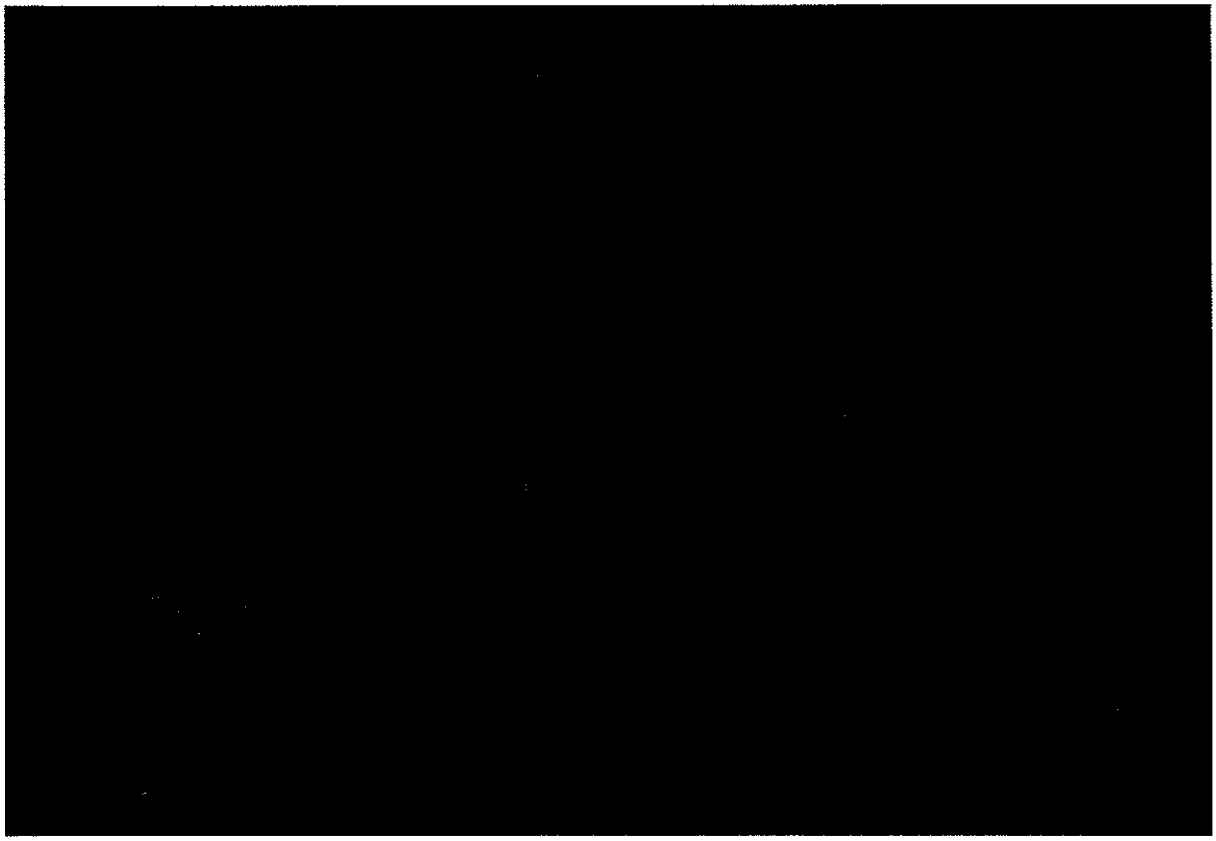
C. Dr. Ferson Studies the Positioning of the Laryngeal Masks Developed by LMA and Ambu

In 2003, Dr. David Z. Ferson, a clinician and researcher at the University of Texas MD Anderson Cancer Center, began a study to compare the anatomical positioning of different airway devices, including the LMs marketed by LMA and Ambu. [redacted] The goal of Dr. Ferson's study was to determine how the differing

[redacted]

designs of airway devices could affect the position and function of those devices. [redacted]

[redacted]



Although Dr. Ferson had used LMs more than a thousand times, he also took numerous precautions to ensure that he properly inserted the devices into the cadavers. [redacted]

[redacted]

D. Dr. Ferson Finds that the Curved Design of Ambu's Laryngeal Masks Increases the Risks Associated with Malpositioning

[redacted]

With respect to the Ambu-LM, Dr. Ferson made two important findings. First, Dr. Ferson concluded, based on the lateral fluoroscopy, that the Ambu mask was among the easiest of the devices to insert because it causes only minimal movement of a patient's larynx during insertion. Berretta Decl., Ex. 14. Second, the CT images revealed that, because of its curved design, the Ambu-LM is positioned (or "seated") higher than the LMA Unique. *Id.* ("The fixed curvature of the shaft of the Ambu Laryngeal Mask causes the cuff to be positioned higher above the hyoid bone than the cuff of the comparably-sized LMA [Unique]"). Dr. Ferson noted that because the Ambu-LM is seated in a higher position, it "increases the risk of compression of the hypoglossal nerve (nerve palsy), which controls the motor function of the tongue." *Id.*

Dr. Ferson noted that while the LMA Unique can also cause nerve damage, such cases are the result of the incorrect positioning of the LMA device, not the device design. [redacted]

[redacted]

E. Dr. Ferson's Research Is Selected for Presentation by the American Society of Anesthesiologists and Published in an Anesthesiology Textbook

In 2004, Dr. Ferson submitted an abstract summarizing the methodology and results of his research to the American Society of Anesthesiologists ("ASA"). [redacted] A committee of physicians from the ASA reviewed the abstract and

confirmed the scientific validity of the research. [redacted] The ASA then selected Dr. Ferson's study for presentation at the 2004 ASA conference. [redacted] Dr. Ferson's abstract was published in *Anesthesiology* (2004) and was generally available to participants in the conference.[2] [redacted] Dr. Ferson also created a scientific poster, which reported the full results of his research. [redacted] Dr. Ferson presented the poster at the conference. [redacted]

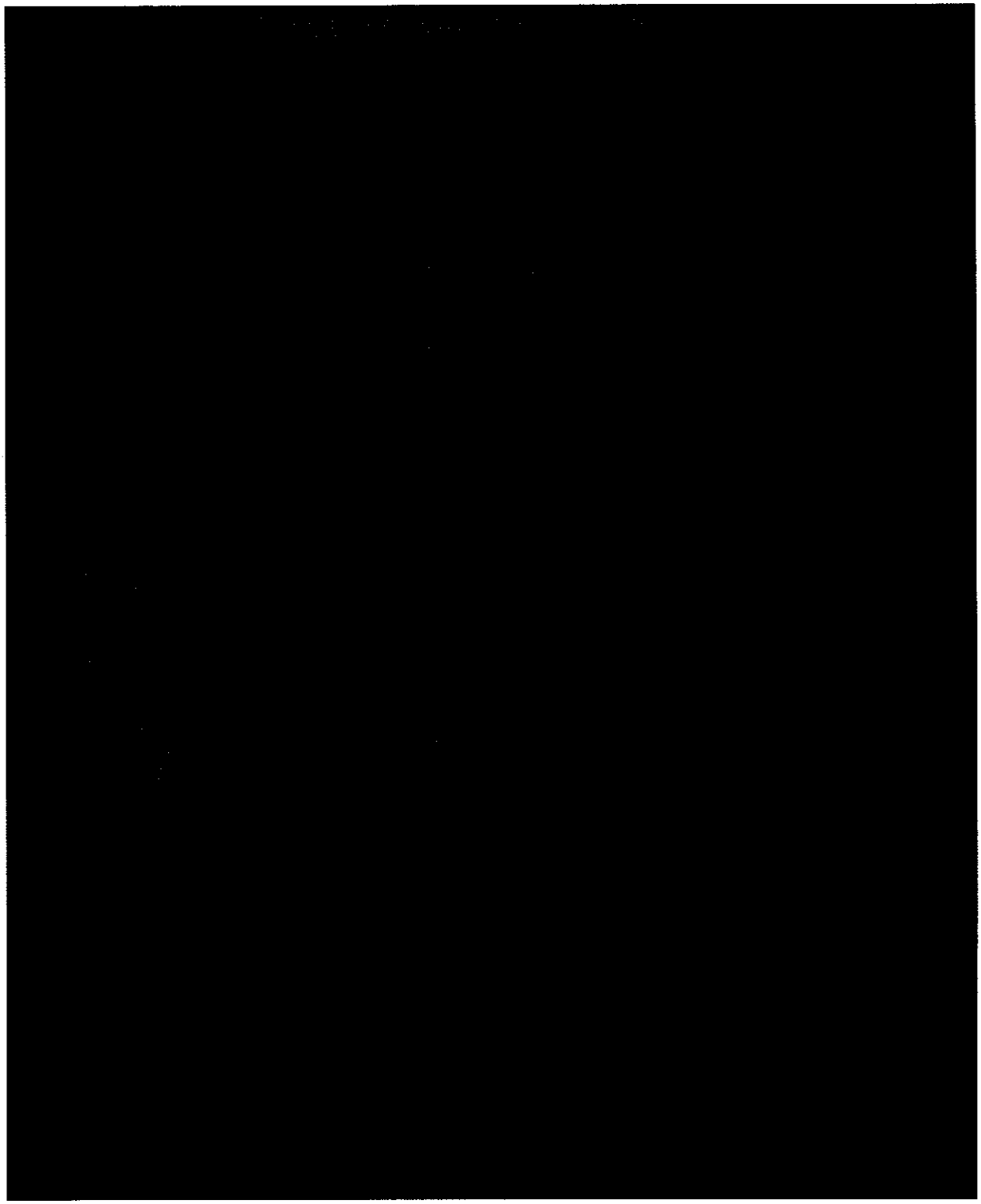
In 2008, Dr. Ferson's research was again published – this time as a chapter in the textbook *Complications in Anesthesiology* (2008) entitled "Safety and Hazards Associated with Tracheal Intubation and Use of Supralaryngeal Airways." Berretta Decl., Ex. 2. *Complications in Anesthesiology* was edited by, among others, Dr. Nikolaus Gravenstein, one of the experts engaged by Ambu in this case. *Id.*; [redacted]

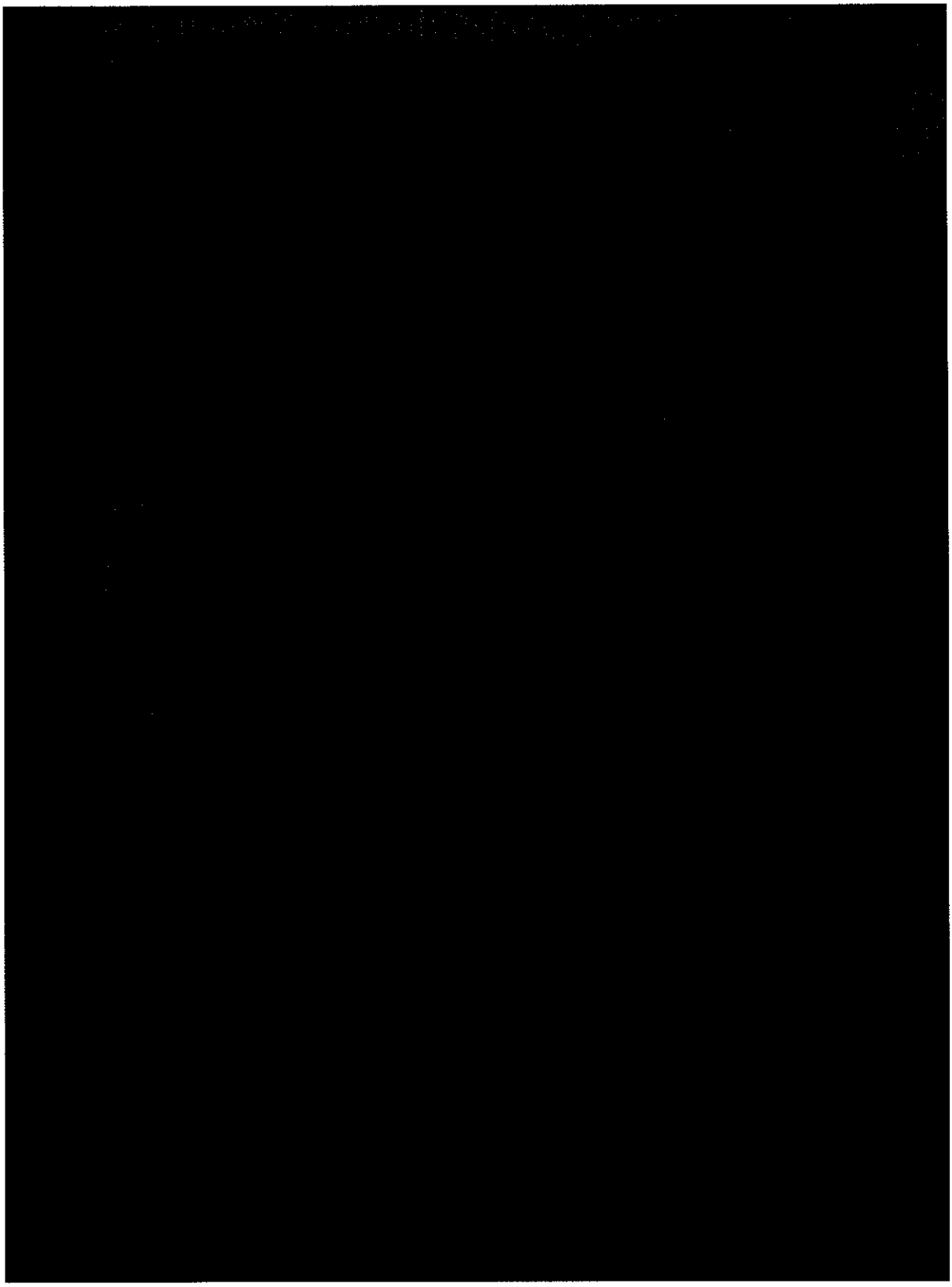
F. Ambu's Employees and Customers Confirm the Results of Dr. Ferson's Research

Clinical experience with the Ambu-LM has confirmed the findings of Dr. Ferson's study. [redacted]

[2] An abstract is a widely-used format for presenting the findings of scientific research. Berretta Decl., Ex. 10. at 48:18-49:2.

[3] [redacted]



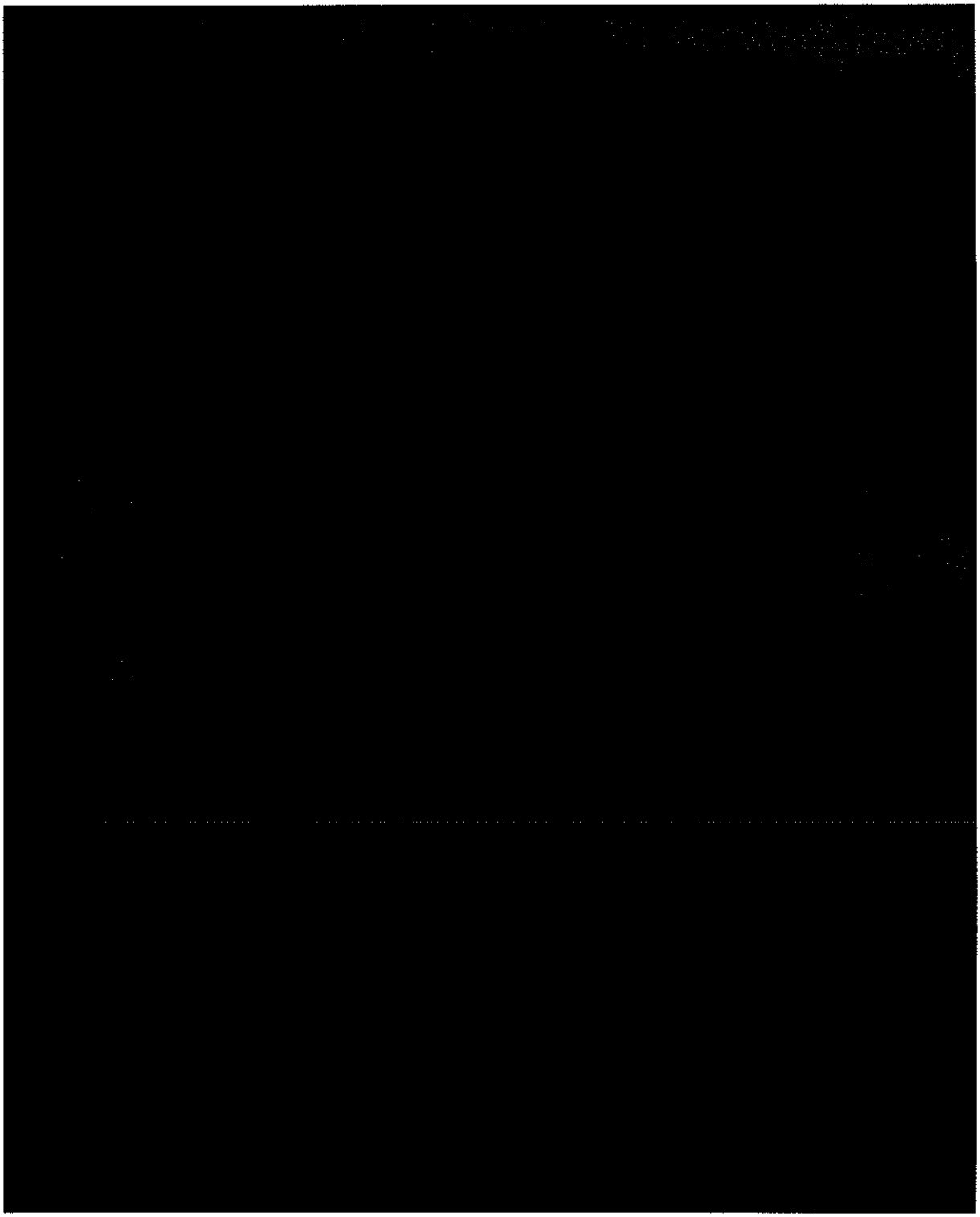


[redacted]

G. Ambu Refuses to Do a Formal Study of Its Device for Fear that It Would Further Confirm Dr. Ferson's Research

[redacted]

H. Ambu Hides Instances of Nerve Damage and Improper Sealing from the Public and the FDA



Pursuant to Ambu's complaint handling procedure and federal regulations, Ambu is

required to record complaints it receives about the safety of its product on a log and open a file dealing with the complaint. [redacted] The complaint files are then periodically inspected by the FDA. Berretta Decl., Ex. 32 at 41:2-4. [redacted] Nor has Ambu logged or opened files on any of the numerous complaints it has received (some of which are set forth above) that the Ambu-LM does not seat or seal properly, thereby creating patient safety issues. [redacted]

It is unclear how many other instances of nerve damage Ambu has failed to record on its complaint logs and open a file and thereby hid from the federal regulators who periodically inspect Ambu's files.[4] [redacted] incident, however, none of these cases [redacted]

Ambu's failure to record the *dozens* of complaints it has received concerning its LMs appears to be consistent with Ambu's prior complaint handling practices. Indeed, the FDA has officially warned Ambu about its failures to properly document complaints about its products – including in cases where those complaints involved patient deaths. Berretta Decl., Ex. 34.

[4] [redacted]

[5] Ambu has apparently taken the position that nerve damage cases do not need to be documented unless a "formal" complaint had been filed (*e.g.*, more than a telephone call from Dr. Agarwal reporting that Ambu's device caused her patient to suffer nerve damage). Berretta Decl., Ex. 8 at 217:23-24, 221:9-12. Federal regulations and Ambu's own internal operating procedures, however, require "***any***...communication that alleges deficiencies related to ... safety" to be "logged in a log book" and recorded on a complaint form. Ex. 31 at AMBU280398-99.

I. LMA Summarizes Dr. Ferson's Research in a Brochure

[redacted]

This summary is faithful to Dr. Ferson's own publications. Berretta Decl., Ex. 2; Ex. 14.

[redacted]

In 2005, LMA asked Dr. Ferson whether they could summarize his research in a brochure to be distributed to anesthesiologists (the "LMA Brochure"). [redacted]

[redacted] Much of the LMA Brochure matches nearly word-for-word the poster that Dr. Ferson presented at the ASA conference and/or the book chapter that Dr. Ferson subsequently published based on his research. *Compare* Berretta Decl., Ex. 48 *with* Ex. 14 *and* Ex. 2.

[redacted]

[redacted]

The LMA Brochure summarizing Dr. Ferson's research was finalized in May 2005 and circulated to anesthesiologists and certified registered nurse anesthetists (CRNAs).

J. Ambu Circulates a Counter-Brochure Falsely Claiming that Dr. Ferson Did Not Authorize LMA's Summary of His Work

By January 2005, Ambu had learned that LMA sales representatives were showing images from Dr. Ferson's study to anesthesiologists. [redacted]

[redacted]

In response to the LMA Brochure, Ambu circulated its own counter-brochure (the "Counter-Brochure"). Berretta Decl., Ex. 42. [redacted]

III. ARGUMENT

Ambu has alleged that LMA committed false advertising under the Lanham Act and related state laws in disseminating the LMA Brochure that summarizes the results of the research conducted by Dr. Ferson and purportedly making oral statements consistent with the content of the LMA Brochure. Berretta Decl., Ex. 44 at 6-12; Berretta Decl., Ex. 45 at 5-6, 10-14.

To succeed on its Lanham Act and related state law claims, Ambu must establish that the LMA Brochure contains false statements. *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997). In particular, Ambu must show either that the statements in the brochure are literally false or that they are literally true but nonetheless convey false messages.[6]

[6] A Lanham Act claim has five elements: "(1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive

Id. LMA is entitled to summary judgment because there is no genuine factual dispute that Ambu cannot satisfy its burden.

A. Summary Judgment Standard for False Advertising Claims

Pursuant to Federal Rule of Civil Procedure 56(c), a party is entitled to summary judgment if there are no genuine issues of material fact. A "genuine issue" of material fact arises if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citations omitted). In that regard, "a mere 'scintilla' of evidence will not be sufficient to defeat a properly supported motion for summary judgment; rather, the nonmoving party must introduce some 'significant probative evidence tending to support the [claim].'" *Summers v. A. Teichert & Son, Inc.*, 127 F.3d 1150, 1152 (9th Cir. 1997) (quoting *Anderson*, 477 U.S. at 249); *accord Eisenberg v. Ins. Co. of N. Am.*, 815 F.2d 1285, 1288 (9th Cir. 1987).

Courts have routinely recognized that summary judgment is appropriate when a plaintiff cannot satisfy the falsity element of a Lanham Act false advertising claim. *See, e.g., Soilworks, LLC v. Midwest Indus. Supply, Inc.*, 575 F. Supp. 2d 1118, 1136 (D. Ariz. 2008) (counter-plaintiff "failed to demonstrate a triable issue as to the falsity of the statement that Durasoil is synthetic"); *Wyatt Tech. Corp. v. Smithson*, No. CV-05-1309, 2006 WL 5668246, at *14 (C.D. Cal. Aug. 14, 2006) (evidence provided failed to "sustain the Lanham Act claims as a matter of law"); *Cairns v. Franklin Mint Co.*, 107 F. Supp. 2d 1212, 1223 (C.D. Cal. 2000) (defendants entitled to summary adjudication where the "uncontroverted evidence demonstrate[d] that defendants' statement . . . is literally true").

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a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products." *Southland Sod*, 108 F.3d at 1139 (footnote omitted). The instant motion addresses only the first element – falsity. LMA is simultaneously filing a second summary judgment motion because Ambu also cannot satisfy either the causation or damages elements of a Lanham Act claim.

B. There is No Genuine Dispute that the Statements in LMA's Brochure Based on Dr. Ferson's Research Are True

Ambu claims that the LMA Brochure violates the Lanham Act because: (i) it contains literally false statements comparing the relative safety of the LMs manufactured by Ambu and LMA; and (2) it conveys an overall false message that LMA's masks are safer than (and therefore superior to) Ambu's masks. Berretta Decl., Ex. 45 at ¶¶ 21-26.

Because the allegedly false superiority claims found in the LMA Brochure are based on a scientific study, those statements are considered "establishment claims." *E.g., Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1248 (11th Cir. 2002) ("If an advertisement cites such testing, the advertisement is labeled as an 'establishment' claim."); *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1492 (1st Cir. 1989) ("'Establishment' claims are statements to the effect that scientific tests establish that a product works."); *Procter & Gamble Co. v. Ultreo, Inc.*, 574 F. Supp. 2d 339, 345 (S.D.N.Y. 2008) (same); *Spalding Sports Worldwide, Inc. v. Wilson Sporting Goods Co.*, 198 F. Supp. 2d 59, 67 (D. Mass. 2002) (same).

A plaintiff, such as Ambu, can satisfy the falsity element of the Lanham Act with respect to an establishment claim in two ways: (1) by showing that the tests upon which the advertisements are based are "not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited"; or (2) by showing that "the tests, even if reliable, do not establish the proposition asserted by defendant." *S.C. Johnson & Son, Inc. v. Clorox Co.*, 930 F. Supp. 753, 779-80 (E.D.N.Y. 1996) (internal quotation marks omitted); *accord Procter & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984); *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992).

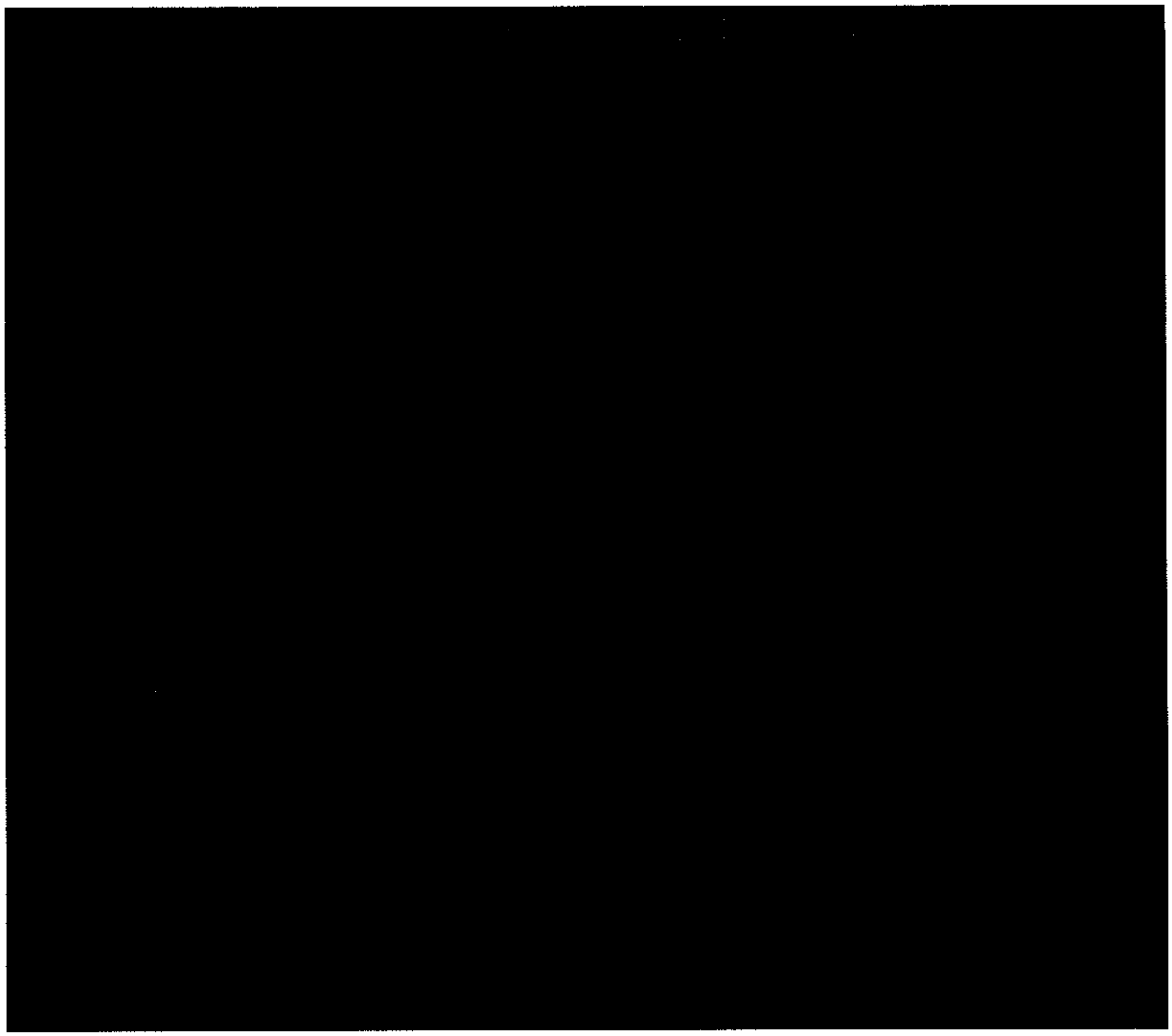
"To ensure vigorous competition and to protect legitimate commercial speech, courts applying this standard should give advertisers a fair amount of leeway, at least in the absence of a clear intent to deceive or substantial consumer confusion." *Rhone-Poulenc Rorer Pharms., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 515 (8th Cir. 1996); *Spalding Sports*, 198 F. Supp. 2d at 69 (same). In particular, "a target audience's special knowledge of a class of products is highly relevant to any claim that it was misled by an advertisement for such a product." *Sandoz Pharms.*

Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 229-30 (3d Cir. 1990). Advertisers should thus be accorded substantial latitude when the establishment claim is targeted at a sophisticated audience that is capable of independently identifying the limitations of the underlying study and the claims made in the advertisements. *See Pfizer, Inc. v. Miles, Inc.*, 868 F. Supp. 437, 456-57 (D. Conn. 1994) (explaining that when "the consumers are physicians who are sophisticated and well informed, they are thus in the position to decide for themselves whether the 'tests' are 'sufficiently reliable to permit one to conclude with reasonable certainty that they establish the proposition for which they are cited'" (quoting *Procter & Gamble*, 747 F.2d at 119)).

In this case, there is no genuine dispute that: (i) Dr. Ferson's research provided a "sufficiently reliable" basis upon which to base an advertisement sent to a sophisticated audience of anesthesiologists and CRNAs; and (ii) that Dr. Ferson's research supports the statements made in the LMA Brochure (as well as any implicit messages conveyed by those advertisements). As a result, Ambu cannot, as a matter of law, show that the LMA Brochure contains false statements within the meaning of the Lanham Act and related state law claims.

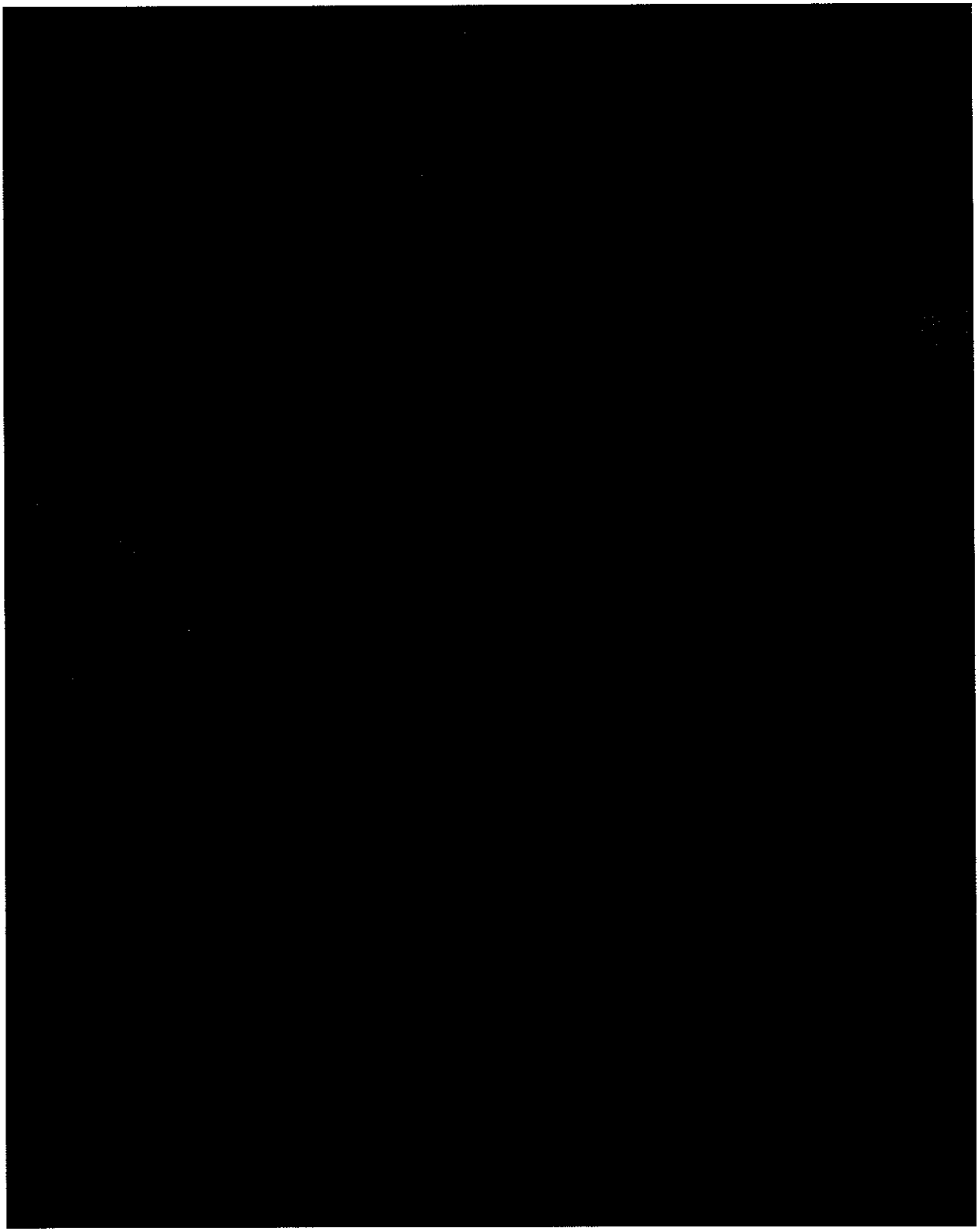
1. Dr. Ferson's research methodology was reliable

As an initial matter, there is no dispute that Dr. Ferson is extremely skilled and experienced in the use of LMs. [redacted]



The scientific reliability of Dr. Ferson's research has also been verified by the repeated selection of the research for presentation and publication. As noted above, Dr. Ferson submitted his research to the ASA in 2004. A panel of ASA members reviewed Dr. Ferson's work and selected the abstract discussing the purpose, methodology, and conclusions of the study for publication in *Anesthesiology* (2004). *Id.* at 48:6-16, 49:5-7, 173:21-174:5. The panel also accepted Dr. Ferson's research for presentation at the 2004 ASA conference. *Id.* at 49:5-7, 139:19-21, 148:20-23. Indeed, Dr. Ferson's research was specially selected for a scientific discussion during the ASA conference. *Id.* at 139:19-21. Subsequently, Dr. Ferson's research was selected for inclusion in an Anesthesiology textbook, which was edited by Ambu's own expert

witness – Dr. Nikolaus Gravenstein. Berretta Decl., Ex. 2; Ex. 10 at 49:18-50:3.



[redacted]

The above admissions are just a representative sample of the numerous internal Ambu "smoking gun" documents that confirm that Dr. Ferson's conclusions were directly on-target. A more complete listing of such documents is found in Sections F and H above.

In support of its claim that Dr. Ferson's research is unreliable, Ambu can offer only the paradigmatic "mere scintilla" of evidence – an opinion from a paid expert witness (Dr. Gravenstein) who attempts to poke holes in Dr. Ferson's methodology by raising questions, but fails to demonstrate insufficient reliability or that Dr. Ferson's conclusions are invalid.[7] It is well-established, however, that a party cannot evade summary judgment simply by offering an expert where – as here – the evidence is otherwise undisputed and contrary to the expert's opinion. *See In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1116 (9th Cir. 1989) ("[W]here the evidence is as clear as that in this record, the court is not required to defer to the contrary opinion of plaintiffs' 'expert.'"); *see also Robinson v. G.D. Searle & Co.*, 286 F. Supp. 2d 1216, 1221 (N.D. Cal. 2003) (rejecting Plaintiff's attempt to offer expert testimony where the "key factual premise on which [the expert's] opinion was based is directly refuted by Plaintiff's admissions" in email messages); *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it

[7] [redacted]

cannot support a jury's verdict."); *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1440 (9th Cir. 1995) (same) (quoting *Brooke Group*, 509 U.S. at 242). As noted above, the undisputed evidence reveals not only the thoroughness of Dr. Ferson's research, but also that Dr. Ferson's conclusions have been repeatedly confirmed by Ambu's own employees and customers.

Finally, [redacted] criticisms, even if accepted as true, do not establish as a matter of law that the research was insufficiently reliable to support the statements in the LMA Brochure. *See, e.g., S.C. Johnson & Son, Inc.*, 930 F. Supp. at 780 ("[T]he fact that the challenged tests are flawed, in and of itself, is insufficient to meet [plaintiff's] burden. Rather, the plaintiff bears the burden of demonstrating that the flaws in the defendant's tests were sufficiently material as to render the defendant's reliance thereon objectively unreasonable."); *L & F Prods., a Div. of Sterling Winthrop, Inc. v. Procter & Gamble Co.*, 845 F. Supp. 984, 1001 (S.D.N.Y. 1994), *aff'd*, 45 F.3d 709 (2d Cir. 1995) ("Although Spic and Span's tests were not perfect, the court finds them sufficiently reliable to support the superiority claim"); *E.R. Squibb & Sons, Inc. v. Stuart Pharms.*, No. 90-1178, 1990 WL 159909, at *17 (D.N.J. Oct. 16, 1990) ("The weaknesses in the conduct of the Whelton Study which Squibb identified and highlighted were troubling. The study had some weaknesses of design, execution and analysis. However, the experiment with ambulatory blood pressure testing was shown to be a worthwhile effort."); *Johnson & Johnson Vision Care, Inc.*, 299 F.3d at 1249 ("The fact that a study's design is imperfect, however, does not render [defendants'] advertisements false."). To the contrary, Dr. Gravenstein's report – like Ambu's "smoking gun" documents – confirms that any flaws Dr. Ferson's work may (or may not) have had, the results of the research were sufficiently reliable to form the basis for the LMA Brochure.

2. Dr. Ferson's research supports LMA's advertising

There is also no genuine dispute that Dr. Ferson's research establishes the explicit propositions asserted by LMA in its brochure, as well as the implicit messages Ambu claims that the brochure conveyed.

a. Dr. Ferson's research supports the explicit claims made in LMA's advertising

Dr. Ferson's research supports the explicit claims made in LMA's advertisements. [redacted] Placing the LMA Brochure side-by-side with the publications summarizing Dr. Ferson's research further establishes that LMA's statements precisely track the conclusions Dr. Ferson reached based on his study:

STATEMENT IN LMA'S ADVERTISEMENTS[8]	STATEMENTS FROM FERSON RESEARCH
"While the size and the pre-curved shape of the Ambu Laryngeal Mask's airway tube make it easy to insert, it also causes the mask to sit much higher than the other two masks, here [in the photo] pressing on the hyoid bone." Berretta Decl., Ex. 48 at LMA00008644.	"The fixed curvature of the shaft of in the AMBU Laryngeal Mask causes the cuff to be positioned higher above the hyoid bone than the cuff of a comparably sized LMA Classic." Berretta Decl., Ex. 14.
"There is a danger that the hypoglossal nerve, which governs motor functions of the tongue can be caught between the mask and the hyoid bone, leading to nerve palsy, and problems with speech and swallowing." Berretta Decl., Ex. 48 at LMA00008646.	"This increases the risk of compression of the hypoglossal nerve (nerve palsy), which controls the motor function of the tongue." Berretta Decl., Ex. 14.

[8] Defying credulity, Ambu and its experts have claimed that virtually *every* sentence in the LMA Brochure is in some way false or misleading. Only "material" false statements, however, can form the basis for a Lanham Act claim. *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990). Ambu has admitted that the only statements in the LMA Brochure that are even arguably material are those dealing with the positioning of its devices and the potential for nerve damage and gastric insufflation, regurgitation, and aspiration. Berretta Decl., Ex. 13 at 104:2-23, 106:7-10.

"Because it sits higher, the Ambu Laryngeal Mask's tip is not in contact with the upper esophageal sphincter." Berretta Decl., Ex. 48 at LMA00008644.	"[T]he higher position of the tip of the AMBU-LM in relation to the cricoid cartilage, as compared to that of the same size LMA Classic, will cause the Ambu-LM to form a less effective seal against the upper esophageal sphincter than the LMA Classic." Berretta Decl., Ex. 2 at LMA00006107.
"The failure to cover the esophagus also increases the risk of gastric insufflation, regurgitation and aspiration." Berretta Decl., Ex. 48 at LMA00008646.	"The higher position of the AMBU-LM causes its cuff tip to be positioned farther away from the upper esophageal sphincter, thereby potentially increasing the chances of regurgitation and aspiration." Berretta Decl., Ex. 2 at LMA00006108.

As is reflected in the above chart, the claims in LMA's advertisements are not only supported by Dr. Ferson's research, they are nearly a carbon copy of his own conclusions.

b. Dr. Ferson's work supports the "messages" Ambu claims are conveyed by LMA's advertising

[redacted] To the extent that these "messages" differ from the explicit claims in the LMA Brochure, each is still supported by Dr. Ferson's research. As noted above, Dr. Ferson specifically concluded (1) "The fixed curvature of the shaft of the AMBU Laryngeal Mask causes the cuff to be positioned higher above the hyoid bone that the cuff of a comparably sized LMA Classic" Berretta Decl., Ex. 2 at LMA00006106; (2) the high positioning of the Ambu device "can cause the hypoglossal nerve to become compressed between the cuff and the hyoid bone, leading to hypoglossal nerve palsy" (nerve damage) (*id.* at LMA00006107); and (3) "The higher position of the AMBU-LM causes its cuff tip to be positioned farther away from the upper esophageal sphincter, thereby potentially increasing the chances of regurgitation and aspiration" (*id.* at LMA00006108).

C. Ambu's State Law Claims Should Also Be Dismissed Because the Challenged Advertisements Are Not False or Misleading

In the absence of any false or misleading statements, the court should also dismiss Ambu's state law claims because "in the Ninth Circuit claims of unfair competition and false advertising under state statutory and common law are substantially congruent to claims under the Lanham Act." *See Walker & Zanger, Inc. v. Paragon Indus., Inc.*, 549 F. Supp. 2d 1168, 1182-83 (N.D. Cal. 2007) (granting motion for summary judgment on both federal and state law claims because all were based on the same underlying statements that plaintiff failed to show were false); *Cleary v. News Corp.*, 30 F.3d 1255, 1262-63 (9th Cir. 1994) (affirming dismissal of Lanham Act claim and holding that the district court properly dismissed the state common-law and statutory claims); *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 316 (C.D. Cal. 1996) (dismissing copyright and Lanham Act causes of action and California unfair competition cause of action).

False or misleading statements are a material element to each of Ambu's four alleged state law claims. *See TYR Sport Inc. v. Warnaco Swimwear Inc.*, No. SACV 08-00529, 2009 WL 1769444, at *14 (C.D. Cal. May 27, 2009) ("To prove trade libel, Plaintiff must show (1) a statement that (2) was false, (3) disparaging, (4) published to others in writing, (5) induced others not to deal with it, and (6) caused special damages.") (citations omitted); *Ariz. Cartridge Remanufacturers Ass'n, Inc. v. Lexmark Int'l, Inc.*, 290 F. Supp. 2d 1034, 1041 (N.D. Cal. 2003), *aff'd*, 421 F.3d 981 (9th Cir. 2005) (dismissing § 17200 (unfair competition) and § 17500 (false advertising) claims because plaintiff failed to prove defendant's practices were misleading, deceptive, or unfair); *Korea Supply Co. v. Lockheed Martin Corp.*, 63 P.3d 937, 950-51 (Cal. 2003) (common law intentional interference with prospective economic relations requires plaintiff to prove "intentional *wrongful* acts on the part of the defendant").[9] Because all of Ambu's state law claims require Ambu to prove that the statements in LMA's advertisements were false or misleading, LMA is entitled to summary judgment of those claims.

[9] In Ambu's intentional interference with prospective economic relations claim, Ambu primarily alleges that LMA "acted wrongfully, through assertions of false and misleading information." Berretta Decl., Ex. 44 at ¶ 43.

IV. CONCLUSION

For the reasons set forth above, LMA respectfully requests that this Court enter summary judgment in favor of LMA on the counterclaims asserted by Ambu.

Respectfully submitted,

Knobbe Martens Olson & Bear LLP

Dated: August 14, 2009

By: /s/Frederick S. Berretta

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CERTIFICATE OF SERVICE

I hereby certify that on August 14, 2009, I caused the foregoing **[REDACTED VERSION] PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT ON AMBU'S LANHAM ACT AND RELATED STATE LAW COUNTERCLAIMS FOR FAILURE TO ESTABLISH FALSE OR MISLEADING ADVERTISING** to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the applicable registered filing users.

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I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Dated: August 14, 2009

Luz Wright

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